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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/933,438

08/20/2001

Yoshiharu Matahira

01503/HG

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05/04/2004

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,438

Applicant(s)

MATAHIRA ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-7,9,11-16,20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-7,9,11-16,20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Request for Continued Examination received on March 25, 2004 is acknowledged. Receipt of Foreign Priority Documents received on August 20, 2001 is acknowledged. Claims **1, 3, 5-7, 9, 11-16, and 20-21** are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites "consist of said anserine or salt thereof of said D-ribose" which is vague and unclear as to what the exact limitation of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 61181357.

JP teaches a solution containing 100 parts of one or more dipeptides such as anserine, carnosine, or balenine with 10 to 400 parts of a sugar such as glucose or ribose in water (excipient).

JP lacks the specific combination of anserine and ribose.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings JP and utilize the instant anserine and ribose mixture. One would be motivated to do so with the expectation of success since JP teaches the suitability of the instant combination anserine and ribose.

*Note that the claims rejected are product claims, thus the intended use "a muscular fatigue controlling composition" is not given patentable weight.

Claims 1, 3, 5-7, 9, and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hageman et al (6,420,342) in view of Harris et al (5,965,596).

Hageman et al teach a nutritional preparation containing ribose for treating various disorders such as fatigue. See claim 18. Ribose is administered in the amount of at least 0.5 g per day daily. See column 5, lines 17-20. Additionally, Hageman et al teach the incorporation of a protein source rich in histidine or histidine itself. The preparation typically contains 5-120g per day daily. Example 1 discloses a preparation containing histidine and ribose in for improving exercise performance.

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Although Hageman teaches the use of histidine or histidine rich proteins, anserine is not specified.

Harris et al teach a composition for increasing anaerobic work in tissues and teaches that creatine and beta-alanylhistidine in muscle content, leads to increased muscle duration during exercise (col. 3, lines 35-46). Harris states that carnosine and anserine are beta-alanylhistidine dipeptides that are involved in the regulation of fatigue and provide an effective way of accumulating histidine in cells. See column 4, lines 58-62. Harris teaches administering chicken broth, which contains anserine and carnosine, to subjects (example 2). Harris teaches the additional use of creatine and carbohydrates, such as sugar, in the composition (claims).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hageman et al and Harris et al and utilize anserine as the histidine source in Hageman et al. One would be motivated to do so since Harris et al teach anserine as a histidine containing dipeptide, which is involved in the regulation of fatigue. Further, Harris et al teach the use of these dipeptides provide an effective way of accumulating histidine in cells. Therefore, one would be motivated to substitute Hageman's histidine with Harris's histidine containing dipeptide, anserine, with the expectation of similar results since Harris teach the functional equivalency of histidine and anserine. Furthermore, Hageman teaches the use of any protein that is rich in histidine and anserine, as taught by Harris, is rich in histidine; therefore one would expect similar results since the criticality lies in histidine in any form.

Claims 1, 3, 5-7, 9, and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al (5,965,596) in view of St. Cyr et al (6,159,942).

Harris et al teach a composition for increasing anaerobic work in tissues and teaches of creatine and beta-alanylhistidine in muscle content, leads to increased muscle duration during exercise (col. 3, lines 35-46). Harris teaches administering chicken broth, which contains anserine and carnosine, to subjects (example 2). Harris teaches the additional use of creatine and carbohydrates, such as sugar, in the composition (claims).

Harris et al does not teach the inclusion of ribose.

St. Cyr et al teaches increasing energy availability in mammals with decreased energy by administering ribose (col. 3, lines 10-16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Harris et al and St. Cyr et al since both teach a method and composition of increasing energy levels. One would be motivated to use anserine and ribose in a composition to obtain an additive effect since both reference teach the use of individual components to increase energy level in muscles. In the absence of showing otherwise, it is prima facie obvious to combine two composition each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. Further, since Harris et al teach the use of a sugar, clearly the compatibility of ribose and the dipeptide are seen.

Response to Amendment

The Rule 132 Declaration under 37 CFR 1.132 filed February 18, 2004 is insufficient to overcome the rejection of claims 1, 3, 5-7, 9, and 11-16 based upon Harris et al (5,965,596) in view of St. Cyr et al (6,159,942).

The declaration is not commensurate in scope since applicant utilizes a specific dosage amount to obtain the synergistic effect and the claims do not reflect this specific concentration. Further, it is not clear if different dosages would yield the same synergistic effect since applicant has not provided evidence of other dosage amounts.

Response to Arguments

Applicant argues that Harris et al administering chicken broth, which not only contains anserine but carnosine, collagen, amino acids, etc. It is argued that there are many components in chicken broth and one would have to pick and choose the instant components with no motivation. Applicant argues that Harris does not teach a sufficient amount to control muscular fatigue. Secondly, applicant argues that Harris does not mention ribose specifically and although simple carbohydrates are mentioned, there are various sugars.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, it is pointed out that the claim language does not exclude other ingredients in the composition. However, inclusion of the claim language of "consisting of" as seen in claims 20-21 would overcome this. The examiner points out that chicken broth inherently contains anserine and Harris clearly teaches the ingestion of anserine. Note column 10 wherein Harris discloses "in one session, 8 milliliters per kilogram body weight of broth containing approximately 40 milligrams per kilogram body weight of

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beta-alanine (**e.g. in the form of anserine and carnosine**) was ingested." Further, it is pointed out that Harris entire invention is focused on increasing the working capacity of muscles and "the method includes ingesting and infusing composition into the body. The compositions are mixtures of compounds capable of increasing the availability and uptake of creatine and of precursors for the synthesis and accumulation of beta-alanylhistidine dipeptides, in human and animal muscles." See column 2. Therefore, it is clear that anserine is utilized in an effective amount to increase work capacity in muscles.

Allowable Subject Matter

Claim 21 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with alternate Fridays off.

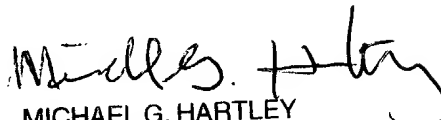
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

May 1, 2004


MICHAEL G. HARTLEY
PRIMARY EXAMINER